

REMARKS

The application is amended and believed to be in condition for allowance.

Amendments to the Claims

Claim 1 is amended to more sharply recite the first and second positioning elements as being configured to removably engage concentrically with each other in a first mode where the elements are engaged and a second mode where the elements are not engaged. The amendment finds support in the specification and the drawing figures as originally filed (e.g., paragraphs [0007] and [0040]-[0045]; Figure 1) and do not introduce new matter.

Substantive Issues - Section 103

The Official Action rejected claims 1-4, 8, 9, and 15-18 under 35 USC 103(a) as being unpatentable over Taylor et al. (US 6,267,765; "TAYLOR") in view of Craig et al. (US 5,507,817; "CRAIG").

The Official Action rejected claims 5, 10-12, and 19 under 35 USC 103(a) as being unpatentable over TAYLOR and CRAIG, and further in view of Rudloff (US 6,010,507; "RUDLOFF").

The Official Action further rejected claims 6-7 and 20-21 under 35 USC 103(a) as being unpatentable over TAYLOR and CRAIG, and further in view of Giannakakos (US 2003/0086772; "GIANNAKAKOS").

The rejections are respectfully traversed for at least the reasons that follow.

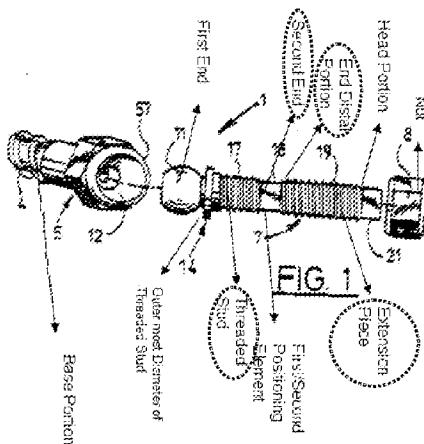
As to claims 1 and 18, the Official Action contends that TAYLOR teaches an extension piece to a vertebral osteosynthesis equipment with a diameter such that a nut can slide over the extension piece.

The Official Action contends that TAYLOR discloses a vertebral osteosynthesis equipment comprising a bony anchor member with a base portion and a threaded stud with a first end and a secondend that is connected to an extension piece having a head portion and end distal portion, where the stud and extension piece have first and second positioning elements configured to engage each other, and where the extension piece is removable, the Official Action specifically referencing column 5, lines 30-35 as to the latter disclosure. The Official Action further contends that the extension piece has a diameter such that the nut can slide over the threaded stud and extension piece.

As indicated in the Figure of page 3 of the Official Action, the Official Action identifies element 19 of TAYLOR Figure 1 as the "extension piece" over which the nut is alleged to slide.

In response, it is respectfully submitted that element 19, as identified by the Official Action, fails to teach or suggest the invention claimed.

The Figure of Official Action page 3 is excerpted below for the Examiner's convenience, wherein four of the labels are circled with dotted lines added for emphasis.



As is plainly disclosed in the Figure above, the extension piece 19 above is threaded in two portions along its entire length, and there is no disclosure in the specification teaching or suggesting either of these threaded portions 19 being configured for the nut 8 to slide over them.

In contrast, each of independent claims 1 and 18 require each of the head portion and the end distal portion of the extension piece to have an outermost external diameter configured such that the nut, in coaxial engagement with said extension piece, slides freely over an entire length of said extension piece.

At best, TAYLOR discloses non-threaded portions at 18 and at 22 where the nut 8 may be able to slide freely. However, the independent claims of the invention require that the

extension piece be configured to provide the nut to slide over its entire length.

TAYLOR makes absolutely clear that the threaded portions at element 19 are configured to mate with the nut 8 in threaded engagement along a greater portion of its entire length.

It is therefore respectfully submitted that TAYLOR fails to teach or suggest this feature recited in independent claims 1 and 18.

Additionally, claims 1 and 18 expressly recite a proximal threaded stud having: i) a first end connected to the base portion, and ii) a free second end opposed to said first end.

The Official Action concedes, on page 4 first paragraph, that TAYLOR fails to teach a threaded stud having a free second end. As indicated in the Figure above, the Official Action identifies the top portion of the thread 17 as the "second end".

The Official Action offers CRAIG as disclosing the use of bone anchors with studs having second free ends connectable with an extension piece via first and second positioning elements.

The Official Action states that one of skill would have found it obvious to have modified TAYLOR with this disclosure of CRAIG so that the length of the bone anchor can be adjusted adjust in order to provide a bone anchor with different lengths.

Applicant respectfully disagrees.

It is firstly respectfully submitted that the first and second positioning elements distinguish over CRAIG. As recited in claims 1 and 18, a bony anchoring member is comprised of a proximal threaded stud and a base portion, the base portion configured to anchor to a vertebra. Hence, the first and second positioning elements of the threaded stud and the extension piece are distinct and spaced from the base portion, and hence would be exposed out of the vertebra when the base portion is anchored to a vertebra. Consequently, the extension piece can be mounted on the threaded stud, or removed therefrom, even after the device is implanted to a vertebra.

CRAIG, in contrast, fails to teach or suggest this configuration. On the contrary, it is not possible to unscrew the distal portion 20, 120 of the medullar tail of CRAIG when the CRAIG device is implanted. In other words, the CRAIG makes no teaching of any element configured for implantation to a vertebra, and instead is directed toward insertion into a fractured humerus wherein the distal portion 20, 120 cannot be removed, as clearly disclosed in Figure 9.

Hence, CRAIG fails to teach either of the base portion or the first and second positioning elements recited in the invention. In particular, CRAIG fails to teach first and second positioning elements configured in a first mode to removably engage with each other, and further configured to disengage from

each other such that the extension piece is not mounted on said proximal threaded stud, as expressly recited by amended claim 1.

Furthermore as to claims 1 and 18, the Official Action contends that one of skill would modify the unthreaded portion of TAYLOR at 18 with the adjustable assembly of CRAIG. TAYLOR teaches that portion 18 between the "second end" from the "end distal portion" as identified by the Official Action, constitutes "a break initiator," (column 5, lines 32-33) so that "Once the set-up has been locked, the posterior portion 19 of each threaded shank 7 is easily broken by virtue of the reduction in cross section formed by the break-initiator region 18," (column 7, lines 46-49). This is illustrated between Figure 4 (with the breakable portion 18 intact) and Figure 9 (breakable portion 18 removed).

It is respectfully submitted that one of skill would have had no rational motivation to modify a device configured to be broken for removal with an adjustable mechanism as disclosed by CRAIG. At the very least, the proposed modification adds cost and complexity to replace a much simpler and satisfactory mechanism (i.e., a reduction in cross section; see column 7, lines 46-48).

The Official Action contends that one of skill would be motivated by a desire for a bone anchor with different lengths. However the proposed modification would impact only the length of the shank extending away from the base portion, and makes no

impact upon the vertebral rod 2 and shackles 3 connecting the bone-anchoring elements together.

On the contrary, it is quite clear from TAYLOR's teaching above that the distal portions of the threaded shank 7 are disposable once implantation is complete. Why, then, would one of skill go through the additional effort and expense to make the length of this disposable portion variable? Applicant has carefully studied the references and can identify no teaching indicating that the proposed modification would be desirable, if indeed reasonable.

The mere fact that references can be combined or modified does not render the resultant combination. The articulated reasoning in an obviousness rejection must possess a rational underpinning to support the legal conclusion of obviousness. *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006).

Here, at best, the modification introduces additional costs while failing to provide any additional benefit. Accordingly, it is respectfully submitted that the modification renders TAYLOR unsatisfactory for its intended purpose, and therefore no rational motivation exists for one of skill to modify TAYLOR with CRAIG as proposed.

Based at least one the foregoing reasons, it is respectfully submitted that independent claims 1 and 18 are patentable over the references applied by the Official Action.

It is further respectfully submitted that claims depending from claims 1 and 18 are patentable at least for depending from a patentable parent claim.

Reconsideration and allowance of the claims are respectfully requested.

From the foregoing, it will be apparent that Applicants have fully responded to the August 7, 2009 Official Action and that the claims as presented are patentable. In view of this, Applicants respectfully request reconsideration of the claims, as presented, and their early passage to issue.

In order to expedite the prosecution of this case, the Examiner is invited to telephone the attorney for Applicants at the number set forth below if the Examiner is of the opinion that further discussion of this case would be helpful.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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